

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION**

JULIE HANIFL,)	
)	
Plaintiff,)	
)	
v.)	No. 4:20-cv-00527-DGK
)	
ETHICON, INC., and)	
JOHNSON & JOHNSON,)	
)	
Defendants.)	

**ORDER DENYING IN PART AND GRANTING IN PART
MOTION TO EXCLUDE DEFENDANTS' EXPERTS**

This product-liability case arises out of the implantation of Defendants' TVT-Exact in April 2011 to treat stress urinary incontinence. Plaintiff alleges the device, a pelvic mesh product, caused dyspareunia, a condition causing severe vaginal pain during intercourse. Now before the Court is Defendant's motion to exclude certain opinions and testimony of Michael Margolis, M.D., an expert witness for Plaintiffs. Defs.' Mot. to Limit Case-Specific Ops. & Test. of Michael Thomas Margolis, M.D., ECF No. 87.

For the following reasons, the motion is DENIED.

Background

Plaintiff experienced stress urinary incontinence and, in April 2011 underwent a procedure that included the implantation of TVT-Exact mesh sling. After the implantation, Plaintiff experienced dyspareunia, lower abdominal pain, the recurrence of urinary incontinence, and a variety of emotional and psychological injuries. Plaintiff attributed these injuries to the TVT-Exact. In October 2011, Plaintiff underwent a procedure to remove a portion of the TVT-Exact mesh, but despite the removal, Plaintiff claims her injuries are ongoing.

Plaintiff retained expert urogynecologist Dr. Margolis, who provided an expert report and sat for a deposition. His opinion relates to the complications experienced by Plaintiff from the TVT-Exact device, the risks and complications in using the TVT-Exact, and alternative treatments available to Plaintiff. Defendants now seek to exclude that portions of Dr. Margolis' testimony.

Standard

When the admissibility of expert testimony is challenged, the district court must make “a preliminary determination of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993). The party seeking to introduce the expert's testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Lauzon v. Senco Products, Inc.*, 270 F.3d 681, 686 (8th Cir. 2001).

Under Federal Rule of Evidence 702, reliability may turn on several factors:

- (a) the expert's scientific, technical or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods;
- and (d) the expert has reliably applied the principles and methods to the facts of the case.

In other words, the proponent must show that the expert's opinions are relevant, the expert is qualified to offer them, and “the methodology underlying [her] conclusions is scientifically valid.” *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006). Doubts should be resolved in favor of admissibility, *id.* at 758, as Rule 702 is “one of admissibility rather than exclusion.” *Arcoren v. United States*, 929 F.2d 1235, 1239 (8th Cir. 1991).

The Court also notes Rule 702 speaks only to its role as gatekeeper. The credibility and weight of testimony is left to the trier of fact. *See, e.g., Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1183 (8th Cir. 1997).

Analysis

I. Dr. Margolis may provide his expert opinions regarding the adequacy of warnings contained in the TVT-Exact device's Instructions for Use.

The Court first considers whether Dr. Margolis may testify as to the adequacy of the warnings contained in the TVT-Exact device's Instructions for Use ("IFU"). Plaintiff proffer's Dr. Margolis' testimony to include the risks of implanting the TVT-Exact, the lack of inclusion of those risks in the IFU, and thus the failure to share important information with implanting physicians. Pl.'s Response 3, ECF No. 90. The Court considers this issued based on the above information only.¹

As a board-certified gynecologist in the field of female pelvic medicine and reconstructive surgery who has written numerous publications in the field, lectured on the subject of sling and mesh complications and pelvic surgery, and performed over one thousand sling procedures, the Court finds Dr. Margolis is qualified to offer an expert opinion as to the sufficiency of the IFU.

The Court does not consider a discussion on the adequacy of the IFU to be an attempt by Plaintiff to testify as to the knowledge of the implanting physician, as Defendants allege. Instead, the Court finds his testimony is based more broadly on the known risks involved in using the TVT-Exact device and whether Defendants adequately provided information on those risks to physicians by inclusion in the IFU. This information is relevant to many of Plaintiff's claims, and thus Defendants motion on the limited issue now before the Court is DENIED.

II. Dr. Margolis may provide his expert opinion regarding the cause of Plaintiff's injury.

Defendants seek to exclude Dr. Margolis' case-specific opinion regarding shrunken, degraded, or contracted mesh causing Plaintiff's injury on the basis that it is purely speculative.

¹ The issue of whether the correct legal framework to consider is informed consent or the learned-intermediary doctrine is not the focus of this motion, and thus the Court refrains from making a decision on the issue if or until such a motion has an opportunity to be fully briefed and considered.

They argue that his reliance on Plaintiff's medical record and the testimony of her surgeon is insufficient to establish his opinion. After reviewing Dr. Margolis' expert report, however, the Court finds his testimony to be the product of sufficiently reliable principles and methods; Defendants' complaints go to the weight and credibility of Dr. Margolis' testimony, not its admissibility. Dr. Margolis has extensive experience with pelvic mesh products and reviewed Plaintiff's medical record from 2010 to 2019. Moreover, in his deposition testimony, Dr. Margolis provides adequate reasoning to explain his conclusions for the role the mesh played in Plaintiff's injuries. Thus, the Court finds no reason to exclude his testimony on this account.

III. Dr. Margolis may provide testimony as to most, but not all, of the alternative-treatment evidence.

Defendants also seek to eliminate any testimony Dr. Margolis may provide regarding alternative treatments, claiming they are irrelevant and unreliable. Defendants identify four alternative treatments in Dr. Margolis' expert report: (1) native tissue repair, (2) a native tissue suture repair known as the Burch procedure, (3) the use of alternative types of slings, and (4) the use of Ultrapro mesh. They seek to limit testimony on all four alternatives.

As this is a motion to limit expert testimony under *Daubert*, and not a motion for summary judgment on Plaintiff's design-defect claim, the Court will not decide the role of alternative designs under Missouri law here. Instead, the Court will focus on the *Daubert* factors, namely the relevance of the proposed testimony, the qualifications of the expert, and the validity of the scientific method used.

Here, the Court finds Dr. Margolis to be a qualified expert in the field of gynecology. Moreover, the existence of alternative procedures with differing risks is relevant to the claims brought by Plaintiff, which include not only design defect but also negligent infliction of emotional distress, failure to warn, negligence, and violation of consumer protection laws, among others.

Thus, the issue here is whether scientifically valid theories support these four proposed alternatives.

Dr. Margolis has testified to widespread use of native-tissue repair, the Burch procedure, and alternative slings in his expert report and deposition testimony. Thus, the Court will not at this time limit his testimony as to those alternative treatments. However, he also testified that he is not aware of any slings made of Ultrapro or mesh with the same properties as Ultrapro. There are also no products using these materials available in the United States. Therefore, the Court will EXCLUDE Dr. Margolis from testifying about Ultrapro or Ultrapro-like mesh products as an alternative design or treatment.

IV. Dr. Margolis may not provide legal-conclusion testimony as to whether the TVT-Exact device was “defective.”

In his expert report, Dr. Margolis described Plaintiff’s injury as resulting from “defects” in the TVT-Exact device. Because Plaintiff has brought a design-defect claim, it is left to the jury to determine whether the device was defective. “[E]xpert testimony on legal matters is not admissible.” *S. Pine Helicopters, Inc. v. Phx. Aviation Managers, Inc.*, 320 F.3d 838, 841 (8th Cir. 2003). Thus, Dr. Margolis is not precluded from discussing the facts underlying his opinions but is EXCLUDED from providing testimony in the form of legal conclusion.

Conclusion

In conformity with the above, Defendants’ motion is DENIED IN PART and GRANTED IN PART.

IT IS SO ORDERED.

Date: March 4, 2021

/s/ Greg Kays
GREG KAYS, JUDGE
UNITED STATES DISTRICT COURT